Adopt Ph 401.01, previously effective 3-26-05 (Doc. #8316), and expired 3-26-13, cited and to read as follows:

CHAPTER Ph 400 CONTINUED STATUS

PART Ph 401 RENEWAL AND REPLACEMENT LICENSES

Ph 401.01 Obtaining and Filing Renewal Applications. Application~~s~~ form Ph A-2 for the renewal of a license to practice pharmacy in New Hampshire may be obtained from, and shall be filed at, the board office.

Adopt Ph 401.03 thru Ph 401.05, previously effective 3-26-05 (Doc. #8316), and expired 3-26-13, to read as follows:

Ph 401.03 Renewal Application Deficiencies. Within 5 days of receipt at the board office, the board shall notify the applicant in writing if the renewal application is deficient. The applicant may then correct the deficiency or file with the board a written request for a hearing before the board.

Ph 401.04 Renewal License Issuance and Denial.

(a) If an applicant timely files an application, complete in all respects, and demonstrates the fulfillment of all the requirements of these rules and RSA 318, the board shall issue a renewal license to practice pharmacy.

(b) Applicants shall register with the New Hampshire Prescription Drug Monitoring Program pursuant to the requirements articulated in RSA 318-B:33, II and Ph 1503.01 (a).

(c) An application failing to meet the requirements of these rules or RSA 318, or both, shall, after the notice and opportunity for hearing**,** be denied.

(d) Applicants who fail to register for the New Hampshire Prescription Drug Monitoring Program pursuant to RSA 318-B:33, II and Ph 1503.01 (a), shall, after the notice and opportunity for hearing, be denied.

Ph 401.05 Duplicate/Replacement Original Certificate of Licensure or Renewal License - Issuance.

(a) If seeking a duplicate or replacement for an original certificate of licensure the applicant shall:

(1) Submit a written request, signed by the pharmacist, to the board for replacement; and

(2) Provide payment of the prescribed fee which shall be $50.

(b) If seeking a duplicate or replacement for an annual renewal license the applicant shall:

(1) Submit a written request, signed by the pharmacist, to the board for a duplicate or replacement; and

(2) No fee shall be assessed for a duplicate or replacement renewal license.

Adopt Ph 401.06, previously effective 2-5-96 (Doc. # 6181-B), as amended effective 2-1-99 (Doc. # 6933), and expired 2-5-04 in the intro. and paragraphs (a) – (d) and (f) – (g), as amended effective 3-26-

05 (Doc. #8316), and expired 2-1-07 in paragraph (e), and expired 3-26-13 in the intro. and paragraphs (a) – (d) and (f) – (g), to read as follows:

Ph 401.06 Reinstatement. A pharmacist whose license to practice pharmacy in this state has been suspended, revoked, voluntarily surrendered or allowed to lapse shall be subject to the following requirements:

(a) File a reinstatement application with the board which shall include at least the following:

(1) Name, address and telephone number of the applicant;

(2) Date of birth; and

(3) Current employment information.

(b) Pay the reinstatement fee of $200;

(c) Submit certificates of attendance/participation in accredited/approved continuing pharmaceutical education courses/programs for a minimum of 15 hours, of which at least 5 hours shall be earned in a live setting. All such continuing education shall have been earned in the period 12 months immediately preceding the date of application for reinstatement;

(d) Successfully complete the jurisprudence MPJE examination as specified in Ph 302.07(a);

(e) If the pharmacist has not held a license to practice pharmacy in this state for a period of 2 years or more, the applicant shall provide:

(1) Notarized affidavit(s) documenting the pharmacist's pharmacy experience during the 2 years immediately preceding the date of his/her application for reinstatement; and

(2) Proof of status of licensure in all states that the pharmacist has been licensed in; and

(f) If the pharmacist has not held a license to practice pharmacy in this state for a period of 5 years or more and has not practiced pharmacy in any other state, the board shall require the completion of a period of pharmacy practice internship prior to reinstatement.

Adopt Ph 401.07 and Ph 402, previously effective 3-26-05 (Doc. #8316), and expired 3-26-13, to read as follows:

Ph 401.07 Gold Certificates.

(a) The board of pharmacy shall issue a gold certificate to any pharmacist who has been regularly licensed as a pharmacist in New Hampshire for 50 consecutive years.

(b) Gold certificates shall be distinctive in coloration and text from other pharmacist licenses issued by the board, and shall be designed to appropriately recognize each recipient pharmacist for his/her half-century of professional practice.

(c) A gold certificate shall be a one-time issuance of honorary nature and confer no right to practice pharmacy upon the recipient.

(d) The awarding of gold certificates shall be made by the board of pharmacy without charge to the recipient.

PART Ph 402 DISCIPLINARY MATTERS

Ph 402.01 Effect of Revocation.

(a) The revocation of a pharmacist license shall permanently withdraw the authority to practice pharmacy in New Hampshire.

(b) A subsequent license may be obtained only by:

(1) Complying with all of the requirements of RSA 318 and these rules regarding the original licensing of pharmacists;

(2) Paying all penalties assessed in connection with the cause for revocation; and

(3) Demonstrating that the cause for revocation does not exist at the time of the subsequent application.

Ph 402.02 Effect of Suspension.

(a) The suspension of a pharmacist license shall temporarily withdraw the authority to practice pharmacy in New Hampshire until the time specified in the order of suspension.

(b) The authority to practice pharmacy in New Hampshire shall be recovered only by:

(1) Complying with all of the requirements specified in the order of suspension;

(2) Complying with all of the requirements of RSA 318 and these rules regarding the renewal of a license to practice pharmacy in New Hampshire; and

(3) Paying all penalties assessed in connection with the cause for suspension.

Ph 402.03 Voluntary Surrender of License.

(a) Any person holding a pharmacist license may voluntarily surrender that license by returning it to the board accompanied by a signed letter stating that the pharmacist intends to permanently surrender his or her license.

(b) The surrender shall be effective upon acceptance by the board and shall immediately preclude the pharmacist from practicing pharmacy in New Hampshire.

(c) A voluntary license surrender, standing alone, shall not prevent the pharmacist from subsequently reapplying for a license.

(d) The voluntary surrender of a license shall have no effect upon the board's authority to:

(1) Investigate violations of the pharmacy laws or the rules of the board by a person licensed at the time the alleged violation occurred; or

(2) Impose disciplinary sanctions based on past conduct which could affect the ability of the former licensee to reapply for a license at a later date.

(e) A voluntary license surrender during the pendency of a disciplinary proceeding shall be recorded in the board's files as "surrendered during disciplinary proceeding."

(f) Nothing in this section shall prohibit the board and a licensee from entering into a settlement agreement or a consent decree relative to any alleged violation of the pharmacy laws or the rules of the board.

Ph 402.04 Hearing. Except as authorized by statute or these rules, a licensee shall not be disciplined except after notice and opportunity for hearing.

Adopt Ph 403.01, previously effective 2-5-96 (Doc. # 6181-B), as amended effective 2-1-99 (Doc. # 6933), and expired 2-5-04 in paragraphs (a) – (f), as amended effective 3-26-05 (Doc. #8316), and expired 2-1-07 in paragraphs (a) and (b), and expired 3-26-13 in paragraphs (c) – (f), cited and to read as follows:

PART Ph 403 CONTINUING EDUCATION REQUIREMENTS

Ph 403.01 Definitions.

(a) "Accredited programs/courses" means continuing education sponsored by providers which are approved by the American Council on Pharmaceutical Education (ACPE) or the Canadian Council on Continuing Education in Pharmacy (CCCEP).

(b) “AMA category I programs” means all programs accepted by the American Medical Association in category I.

(c) "Board approved programs/courses" means continuing education which has been reviewed and recommended by the continuing education advisory council and approved by the board of pharmacy or continuing education programs approved by a Canadian provincial or territorial pharmacy licensing authority.

(d) “Certificate of accredited/approved CEU's” means a document, issued to a particular pharmacist by an accredited or approved provider certifying that the pharmacist has satisfactorily completed a specified number of CEU's. Such certificates include a unique program identification number issued by the accrediting/approving provider.

(e) “Continuing education” means accredited or approved post-licensure pharmacy education designed to maintain professional competence in the practice of pharmacy, improve professional skills, and preserve pharmaceutical standards for the purpose of protecting the health and welfare of the citizens in the state of New Hampshire. Continuing education includes study in one or more of the general areas of the properties and actions of drugs and dosage forms, etiology, characteristics and therapeutics of the disease state, socio-economic and legal aspects of health care.

(f) “Continuing education advisory council (CEAC)” means a group of individuals appointed by the board of pharmacy to serve in an advisory capacity on continuing education.

(g) “Continuing education unit (CEU)” means 10 contact hours of participation in accredited or board approved continuing education courses/programs.

(h) “In-state approved provider” means an individual, institution, organization, association, corporation or agency located in the state of New Hampshire in no manner affiliated with any manufacturer or distributor of supplies or services used in the practice of pharmacy, who is approved by the board of pharmacy to provide continuing pharmacy education according to Ph 403.12.

Adopt Ph 403.02, previously effective 2-5-96 (Doc. # 6181-B), as amended effective 2-1-99 (Doc. # 6933), and expired 2-5-04 in paragraphs (a) – (f), as amended effective 3-26-05 (Doc. #8316), and expired 2-1-07 in paragraph (g), and expired 3-26-13 in paragraphs (a) – (f), to read as follows:

Ph 403.02 Renewal Requirements.

(a) The board of pharmacy shall not issue licensure renewals unless the pharmacist indicates on the renewal application, and under penalty of unsworn falsification, that he/she has completed the minimum required hours of accredited/approved continuing pharmaceutical education courses/programs according to Ph 403.02(d). An incomplete renewal application shall be returned to the applicant.

(b) Continuing education shall be required of all licensed, active or inactive pharmacists who apply for license renewal.

(c) Pharmacists submitting applications for the first annual licensure renewal shall be exempt from the continuing education requirements.

(d) All pharmacists licensed in New Hampshire shall acquire 1.5 CEU's during the 12 months immediately preceding the license renewal date of January 1st. At least 0.5 CEU's shall be earned in a live setting.

(e) Continuing education credits shall not be recognized for any repeat program attended or completed. Repeat programs shall be identified as any program, live or correspondence, which carries the same ACPE, CME or any board of pharmacy program identification number.

(f) The pharmacist shall retain all certificates and/or other documented evidence of participation in an approved/accredited continuing education program/course for a period of at least 3 years. Such documentation shall be made available to the board for random audit and/or verification purposes.

(g) Not less than 10% of the registrants shall be randomly selected each year by the board for determinations of compliance with Ph 403.02.

Adopt Ph 403.03 - Ph 403.13, Ph 404, and Ph 405, previously effective 3-26-05 (Doc. #8316), and expired 3-26-13, to read as follows:

Ph 403.03 Excess CEU's. Excess CEU's earned in one licensure period shall not be carried forward into the new licensure period for the purpose of fulfilling that year's continuing education prerequisite for licensure renewal.

Ph 403.04 CEU's from Other States. The board of pharmacy shall accept comparable continuing education units which have been approved by other boards of pharmacy provided they meet or exceed the requirements as set forth in Ph 403.

Ph 403.05 Credit for Instructors of Continuing Education.

(a) Any pharmacist, whose primary responsibility is not the education of health professionals, who leads, instructs or lectures to groups of nurses, physicians, pharmacists or others on pharmacy related topics in organized continuing education or in-service programs, shall be granted continuing education credit for such time expended during actual presentation.

(b) Any pharmacist whose primary responsibility is the education of health professionals shall be granted continuing education credit only for time expended in leading, instructing, or lecturing to groups

of physicians, pharmacists, nurses or others on pharmacy-related topics outside his/her formal course responsibilities in a learning institution.

(c) Credit for presentation of in-service training programs or other lectures shall be granted only once for any given program or lecture.

(d) A maximum of 4 hours in this category may be applied toward fulfilling the total continuing education yearly requirements. However, these hours shall not be considered in fulfilling the live requirements as set forth in Ph 403.02(d).

Ph 403.06 Postgraduate Pharmacy Curricula.

(a) A pharmacist who matriculates in a postgraduate pharmacy curriculum or post graduate pharmacy program shall be awarded CEU's for satisfactory completion of each course within said curriculum or program.

(b) The course work for which CEU credit is provided pursuant to (a) above, shall provide instruction in one or more of the following areas of study:

(1) Pharmacy;

(2) Pharmaceutical calculations;

(3) Pharmaceutical chemistry;

(4) Pharmacology;

(5) Therapeutics;

(6) Pharmacy management;

(7) Pharmaceutical jurisprudence; or

(8) Other course work related to the pharmaceutical sciences.

Ph 403.07 Audio/Visual Continuing Education.

(a) Continuing education credit may be claimed for the completion of home study audio and/or video cassette tape programs/courses, provided that such programs require the completion of a written exam by the pharmacist to be scored by the provider of such programs.

(b) Audio/visual continuing education programs, including satellite transmissions, which provide for group discussion and include a facilitator shall, be allowed as live programming.

(c) Webinars that are ACPE approved and contain an “L” in the program approval number shall be allowed as live programming.

Ph 403.08 Waiver. The board shall waive some or all of the continuing education requirements, for a period not to exceed one calendar year, for such hardships as illness or incapacity. Written request for waiver shall be submitted to the board for consideration.

Ph 403.09 Military Personnel. Military personnel or spouses shall not be exempt from the continuing education requirements, because correspondence programs/courses are available, but shall be exempt from the live requirement if assignment is in a foreign country.

Ph 403.10 Reinstatement. Any pharmacist desiring reinstatement of licensure shall show evidence of completion of at least 1.5 CEU's, according to Ph 403.02(d) and earned in the 12 months immediately preceding the date of application for reinstatement.

Ph 403.11 Penalty. Any pharmacist who alters, forges, or intentionally falsifies, or causes to be altered, forged, or falsified any information, documents, or records required to be kept or submitted by this rule shall be subject to disciplinary action under RSA 318:29, II. Falsification of records shall constitute misconduct.

Ph 403.12 In-State Approved Providers of Continuing Pharmacy Education.

(a) An individual, institution, organization, association, corporation or agency located in the state of New Hampshire desiring to be an in-state provider of continuing pharmacy education shall notify the board in writing subject to the criteria set forth in Ph 403.12 (d)(1) - (10).

(b) Approval of in-state providers shall be valid for a period of 2 years from date of approval after which time re-application shall be necessary.

(c) In-state providers who desire to become approved by the board shall provide their educational qualifications and an example of a program to the CEAC committee for review.

(d) In state providers shall comply with the following:

(1) The provider shall designate a responsible person for the administration of the continuing pharmacy education program and liaison with the CEAC and the board;

(2) Providers shall award continuing pharmacy education credit to successful participants in terms of CEU's;

(3) The provider shall maintain a list of successful participants for each program provided for a period of not less than 3 years;

(4) The list required by (3) above shall be made available to the CEAC and the board on request;

(5) The provider shall award to each successful participant a certificate containing at least the following information:

a. The name of the provider;

b. The completion date of the continuing education program;

c. The name of the participant;

d. The title of the program;

e. The number of CEU's the program has been assigned; and

f. The board of pharmacy program identification number.

(6) All programs shall be referenced as "live" or "correspondence" in nature;

(7) Providers shall present their participants with a statement of goals and objectives prior to each continuing pharmacy education program and involve their participants in identifying their own educational needs;

(8) Providers shall develop and employ evaluation techniques that will assess the effectiveness of the continuing pharmacy education offerings and the level of fulfillment of the stated objectives with the goal of continual improvements;

(9) Providers shall utilize an evaluation mechanism for the purpose of allowing each participant to assess his/her achievement of personal objectives; and

(10) Providers shall assign an identification number to every program presented according to the numbering system designated by the board of pharmacy.

(e) Continuing education programs presented by in-state approved providers shall not have to be submitted to the CEAC for review and approval by the board.

(f) In-state approved providers of continuing pharmacy education shall publicize programs and/or coursework by referencing endorsement by the board only as follows: "This program is approved by the New Hampshire Board of Pharmacy for _____ CEU's of continuing pharmacy education". Programs shall also be referenced as "live" or "correspondence" in nature.

(g) Board approval of in-state provider shall be revoked following notice and opportunity to be heard upon a finding that the provider has engaged in fraud or dishonesty or is no longer in compliance with one or more of the criteria of (d) above.

Ph 403.13 Continuing Education Advisory Council Membership.

(a) The advisory council shall consist of not less than 6, nor more than 10 members, at least one of whom shall be a member of the board.

(b) The term of appointment shall be for 3 years and shall be served until the expiration date or until a successor has been named. Should a vacancy occur, a successor shall be appointed to serve the unexpired term.

(c) The advisory council shall submit all recommendations to the board for its implementation and/or approval.

(d) It shall be the duty of the advisory council to:

(1) Elect from its membership a chairman and a secretary annually;

(2) Recommend to the board the standards and specifications required of programs/courses which might be acceptable for board approval in fulfilling continuing education requirements;

(3) Recommend programs which meet the standards and specifications adopted;

(4) Recommend the number of CEU's granted for the satisfactory completion of approved programs; and

(5) Provide such other assistance to the board necessary in the implementation and maintenance of the continuing education licensure renewal prerequisite.

(e) The advisory council shall meet a sufficient number of times annually to properly perform its functions.

(f) The advisory council quorum shall be equal to the majority of the council membership.

PART Ph 404 STANDARDS FOR COMPOUNDING AND DISPENSING STERILE AND NON-STERILE PHARMACEUTICALS

Ph 404.01 Purpose and Scope.

(a) The purpose of this part is to provide all compounders with guidance on applying good compounding practices for the preparation of non-sterile and sterile compounded formulations for dispensing and/or administration to humans and animals. Compounding is an integral part of pharmacy practice and is essential to the provision of healthcare.

(b) The board shall require all compounders engaging in compounding in all situations to adhere to and comply with the current edition of the United States Pharmacopeia including but not limited to Chapters 795 (USP 795) and 797 (USP 797), following those guidelines that apply to their practice setting. These chapters shall be reviewed in full and followed by compounders prior to non-sterile or sterile pharmaceutical compounding. These regulations shall apply to non-sterile and sterile compounding of medications.

Ph 404.02 Definitions.

(a) "Active pharmaceutical ingredients" means chemicals, substances, or other components of articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases in humans or animals or for use as nutritional supplements.

(b) "Added substances" means the ingredients necessary to prepare the drug product but are not intended or expected to cause human pharmacological response if administered alone in the amount or concentration contained in a single doses of the compounded preparation. The term "added substances" includes the terms "inactive ingredients", "excipients", and "pharmaceutical ingredients."

(c) "Ante-area" means:

(1) An ISO Class 8 or better area where personal **perform** hand hygiene and garbing procedures, staging of components, order enter, CSP labeling, and other high-particulate-generating activities are performed;

(2) A transition area that:

a. Provides assurance that pressure relationships are constantly maintained so that air flows from clean to dirty areas; and

b. Reduces the need for the heating, ventilating, and air-conditioning (HVAC) control system to respond to large disturbances.

(d) "Aseptic processing" means a mode of processing pharmaceutical and medical products that involves the separate sterilization of the product and of the package containers, closures or packaging

material for medical devices and the transfer of the product into the container and its closure under at least ISO Class 5 conditions.

(e) "Beyond-use date (BUD)**"** is the date after which a compounded preparation should not to be used; determined from the date the preparation is compounded.

(f) "Biological Safety Cabinet (BSC)" means a ventilated cabinet for CSPs, personnel, product, and environmental protection having an open front with inward airflow for personnel protection, downward high-efficiency particulate air (HEPA)-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection.

(g) "Buffer area" means an area where the primary engineering control (PEC) is physically located.

(h) "Clean room" means a room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class. Microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear are not exceeded for a specified cleanliness class.

(i) "Component" means any ingredient used in the compounding of a drug preparation, including any active ingredient or added substance that is used in its preparation.

(j) "Compounder" means a licensed professional authorized by the appropriate jurisdiction to perform compounding pursuant to a prescription or medication order by a licensed prescriber.

(k) "Compounding" means the preparation, mixing, assembling, altering, packaging, and labeling of a drug, drug-delivery device, or device in accordance with a licensed practitioner's order, or initiative based on the practitioner/patient/pharmacist/compounder relationship in the course of professional practice, and includes the following:

(1) Preparation of drug dosage forms for both human and animal patients;

(2) Preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns;

(3) Reconstitution or manipulation of commercial products that may require the addition of one or more ingredients;

(4) Preparation of drugs or devices for the purposes of, or as an incident to research clinical or academic teaching, or chemical analysis; and

(5) Preparation of drugs and devices on the order of a practitioner, which may be sold to the practitioner for use in his or her office to administer to a specific patient, in limited quantities, but not for resale.

(l) "Compounding Aseptic Containment Isolator (CACI)" means a compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations.

(m) "Compounding Aseptic Isolator (CAI)" means a form of isolator specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes.

(n) "Critical area" means an ISO Class 5 environment.

(o) "Critical site" means a location that includes any component or fluid pathway surfaces such as vial septa, injection ports, beakers or openings such as opened ampules or needle hubs exposed and at risk of direct contact with air including ambient room or HEPA filtered, moisture such as oral and mucosal secretions, or touch contamination. Risk of microbial particulate contamination of the critical site increases with the size of the openings and exposure time.

(p) "Direct Compounding Area (DCA)" means an area within the ISO Class 5 primary engineering control (PEC) where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.

(q) "Disinfectant" means an agent that frees from infection, usually a chemical agent but sometimes a physical one, and that destroys disease-causing pathogens or other harmful microorganisms but might not kill bacterial and fungal spores. It refers to substances applied to inanimate objects.

(r) "First air" means the air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.

(s) "Hazardous drugs" means any drug which in studies of animals or humans have been classified as carcinogenic, toxic to development or reproduction, or toxic to organs.

(t) "Labeling" means a term that designates all labels and other written, printed, or graphic matter on an immediate container of an article or preparation or on, or in, any package or wrapper in which it is enclosed, except any outer shipping container. The term "label" designates that part of the labeling on the immediate container.

(u) "Limited quantities" means a batch with 50 or less dosage units provided to a hospital or practitioner to administer to their own patient.

(v) "Manufacturing" means the production, preparation, propagation, conversion or processing of a drug or device, either directly or indirectly, by large volume extraction from substances of natural origin, or independently by means of chemical or biological synthesis, and includes any packaging or repackaging of a substance or labeling or relabeling of its container, and the promotion and marketing of such drugs and devices for resale.

(w) "Media-fill test" means a test used to qualify aseptic technique of compounding personnel or processes and to ensure that the processes used are able to produce sterile product without microbial contamination. During this test, a microbiological growth medium such as Soybean–Casein Digest Medium is substituted for the actual drug product to simulate admixture compounding.

(x) "Memorandum of understanding" means a document specific to the preparation(s) provided to a practitioner by a compounder outlining the distinct responsibilities of the compounder and practitioner.

(y) “Multiple-dose container” means a multiple-unit container for articles or preparations intended for parenteral administration only and usually containing antimicrobial preservatives.

(z) “Negative pressure room” means a room that is at a lower pressure than the adjacent spaces and, therefore, the net flow of air is into the room.

(aa) “Pharmacy bulk package” means a container of a sterile preparation for parenteral use that contains many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile syringes.

(ab) “Positive pressure room” means a room that is at a higher pressure than the adjacent spaces and, therefore, the net airflow is out of the room.

(ac) “Preparation” means a compounded drug dosage form or dietary supplement or a device to which a compounder has introduced a drug.

(ad) “Primary Engineering Control (PEC)” means a device or room that provides an ISO Class 5 environment for the exposure of critical sites when compounding CSPs. Such devices include, but are not limited to, laminar airflow workbenches (LAFWs), BSCs, CAIs, and CACIs.

(ae) “Product” means a commercially manufactured sterile drug or nutrient that has been evaluated for safety and efficacy by the FDA.f

(af) “Segregated compounding area” means a designated space, either a demarcated area or room, that is restricted to preparing low-risk level CSPs with 12-hour or less BUD. This area shall contain a device that provides unidirectional airflow of ISO Class 5 air quality for preparation of CSPs and shall be oid of activities and materials that are extraneous to sterile compounding.

(ag) “Single-dose container” means a single-unit container for articles or preparations intended for parenteral administration only. It is intended for a single use. A single-dose container is labeled as such. Examples of single-dose containers include prefilled syringes, cartridges, fusion-sealed containers, and closure-sealed containers when so labeled.

(ah) “Sterilization by Filtration” means passage of a fluid or solution through a sterilizing grade membrane to produce a sterile effluent.

(ai) “Sterilizing grade members” means that membranes that are documented to retain 100% of a culture of 107 microorganisms of a strain of Brevundimonas (Psuedomonas) diminuta per square centimeter of membrane surface under a pressure of not less than 30 psi or 2.0 (bar). Such filter membranes are nominally at 0.22-um or 0.2-um nominal pore size, depending on the manufacturer’s practice.

(aj) “Terminal Sterilization” means the application of a lethal process, such as steam under pressure or autoclaving, to sealed containers for the purpose of achieving a predetermined sterility assurance level of usually less than 10-6, or a probability of less than one in one million of a non-sterile unit.

(ak) " Unidirectional flow" means the airflow moving in a single direction in a robust and uniform manner and at a sufficient speed to reproducibly sweep particles away from the critical processing or testing area.

(al) "United States Pharmacopia" means a legally recognized compendium of standards for drugs.

(am) "Vehicle" means a component for internal and external use that is used as a carrier for diluent in which liquids, semisolids or solids are dissolved or suspended. Examples include, but are not limited to, water, syrups, elixirs, oleaginous liquids, solid and semisolid carriers and proprietary products.

Ph 404.03 Non-sterile Pharmaceutical Compounding.

(a) Compliance with USP 795 and all applicable USP chapters related to non-sterile compounding shall be followed.

(b) There are 3 general categories of non-sterile compounding described in this section that require different levels of experience, training and physical facilities. The 3 categories shall be:

(1) Simple compounding which includes reconstituting or manipulating a commercial product that might require the addition of one or more ingredients as directed by the manufacturer or preparing a product that has a USP compounding monograph or appears in a peer reviewed article that contains the quantities for all components, procedures and equipment with the exception of pre-measured compounding kits;

(2) Moderate compounding which includes making a preparation that requires complex calculation or procedures to determine quantities of components per preparation or per individualized dosage units, making a preparation for which stability data for that specific formulation is not available and mixing 2 or more manufactured creams when the stability of the mixture is unknown; and

(3) Complex compounding which includes making a preparation that requires specialized training, environment, facilities, equipment, and procedures such as transdermal dosage forms and modified-release preparations.

(c) Responsibilities of the compounder shall include:

(1) Compounding preparations of accepted strength, quality, and purity and in accordance with the prescription or medication order;

(2) Dispensing the finished preparation, with appropriate packaging and labeling, and in compliance with RSA 318:47-a, federal law, and other regulatory agencies where appropriate;

(3) Maintaining proficiency in drug or dietary supplement compounding;

(4) Ensuring the quality of compounded preparation by adhering to the general principles listed in USP 795 and all applicable compounding laws, guidelines and standards including but not limited to:

a. Training of all the personnel shall be current and documentation of such kept on site;

b. Compounding ingredients shall be purchased from reliable sources and be properly stored;

c. Bulk component containers shall be properly labeled and SDS sheets available;

d. Equipment used shall be clean, properly used and maintained;

e. Environment shall be suitable to prevent cross contamination including the use of powder containment systems if API's are used or powder is created through manipulation of solid dosage forms or emptying of powder containing vials;

f. Compounding personnel shall wear appropriate and clean clothing. Protective apparel such as lab coats gowns, gloves, shoes, or masks shall be worn as necessary to protect personnel from chemical exposure and/or contamination;

g. Only authorized personnel shall be allowed in the compounding area;

h. Compounding conditions and procedures shall be such to prevent errors;

i. There shall be assurance that processes are always carried out as intended or specified and are reproducible;

j. All aspects of compounding shall be properly documented;

k. Procedures and records exist for investigating and correcting failures or problems in compounding and testing; and

l. A valid and reproducible recall policy and procedure.

(5) The compounder shall be responsible for ensuring that each individual incidence of the compounding process meets the criteria in USP 795.

(d) The compounding area shall adhere to the general principles listed in USP 795 guidelines including but not limited to:

(1) Adequate space specifically designated for compounding and storage of equipment and materials;

(2) Be clean, orderly, and properly maintained;

(3) Easily accessible hand washing, hot and cold water, soap or detergent, and an air-drier or single-use towels must be present;

(4) Be located in a separate area from sterile compounding area;

(5) Purified water shall be used for compounding non-sterile drug preparations when formulations indicate the inclusion of water;

(6) Disposal of all hazardous drug wastes shall comply with applicable federal and state regulations; and

(7) All personnel who perform routine custodial waste removal and cleaning activities in storage and preparation areas for hazardous drugs shall be trained in appropriate procedures to protect themselves and prevent contamination including spill clean ups.

(e) All equipment and utensils used in compounding shall comply with the following:

(1) Be of appropriate design and capacity for the required task;

(2) Automatic, mechanical, electronic, or other equipment used in compounding shall be routinely inspected, calibrated, or checked according to the manufacturer's recommendations to ensure proper performance; and

(3) Equipment shall be stored to protect it from contamination. It shall be located in an area to facilitate its use, cleaning and maintenance.

(f) Component Selection, Handling and Storage shall be subject to the following requirements:

(1) A United States Pharmacopeia (USP), National Formulary (NF), or Food Chemicals Codex (FCC) substance shall be the recommended source of ingredients for compounding all preparations.

(2) If ingredients are from a non-FDA registered facility the professional judgment of the compounder shall be used in selecting an acceptable and reliable source and shall establish purity and safety including obtaining a certificate of analysis from the manufacturer or qualified third party;

(3) Components for compounding shall be properly labeled with lot numbers and expiration dates. If a component is transferred from the original container to a new container, the new container shall be labeled with the component name, original supplier, lot or control number, transfer date, and expiration date and shall provide integrity that it is equal to or better than the original container;

(4) For components that do not have expiration dates assigned by the manufacturer or supplier the compounder shall label the container with the date of receipt and assign a conservative expiration date not to exceed 3 years after receipt;

(5) Written control procedures shall be established to monitor the output and to validate the performance of those compounding processes that might be responsible for causing variability in the final drug product, including but not limited to, the following:

a. Capsule weight variation;

b. Adequacy of mixing to insure uniformity and homogeneity;

c. Clarity, completeness, or pH of solutions; and

d. Observation of instability;

(6) When compounding with manufactured drug products, the compounder shall consider all ingredients, including excipients, present in the drug product relative to the intended use of the compounded preparation and the effect of manipulating the drug product on the therapeutic appropriateness and stability of the components;

(7) All components used in compounding shall be stored as directed by the manufacturer, or according to USP or NF requirements, in a clean, dry area under appropriate temperature conditions. All components shall be stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first. All containers shall be properly labeled; and

(8) Use of pre-measured compounding kits shall adhere to all USP 795 standards, including the level of non-sterile compounding and utilizing a master formulation record and a compounding record.

(g) The following provisions of USP 795 shall be followed when determining stability and beyond use dating:

(1) Compounders shall consult and apply drug-specific and general stability information and literature when available;

(2) Compounders shall consider the following when determining BUDs:

a. Nature of the drug and degradation mechanism;

b. Dosage form and its components;

c. Potential for microbial proliferation in the preparation;

d. Container when it is packaged;

e. Intended duration of therapy; and

f. Expected storage conditions;

(3) When using manufactured solid dosage forms to prepare a solution or aqueous suspension, the compounder shall also consider factors such as hydrolysis, oxidation, and the freeze - thaw property of the final preparation;

(4) When a manufactured product is used as the source of the active pharmaceutical ingredient for a non-sterile compounded preparation, the product expiration date shall not be used to assign a BUD for the compounded preparation. Instead the compounder shall refer to the manufacturer for stability information and to the literature for applicable information on stability, compatibility, and degradation of ingredients. All data shall be carefully interpreted in relation to the actual compounded formulation;

(5) Susceptible preparations should contain suitable antimicrobial agents to protect against bacteria, yeast, and mold contamination inadvertently introduced during or after the compounding process. When antimicrobials are contraindicated, storage of the preparation at controlled cold temperature shall be necessary to retard microbial growth.

Appropriate patient or caregiver instruction regarding storage and handling shall be essential;

(6) In the absence of reliable stability information or published date the following general guidelines for maximum BUD shall be:

a. A maximum of 6 months for non-aqueous formulations;

b. A maximum of 14 days under refrigeration for water-containing oral formulations; and

c. A maximum of 30 days for water containing topical, dermal and mucosal liquid and semisolid formulations.

(7) The BUD shall not exceed the expiration date of the API or any other component.

(h) The compounder shall ensure that the containers and closures used in packaging compounded preparations meet the following USP requirements:

(1) The containers and closures shall be made of clean material in order not to alter the quality, strength, or purity of the compounded preparation;

(2) Container-drug interaction shall be considered for substances that have sorptive or leaching properties; and

(3) Containers and closures shall be handled and stored in such a way as to prevent contamination.

(i) Compounders shall comply with the following requirements regarding compound documentation;

(1) Documentation, written or electronic, shall be kept for 4 years;

(2) Documentation shall comply with state and federal laws;

(3) Documentation shall not be required when preparing a compounded preparation according to the manufacturer's labeled instructions;

(4) The record may be a copy of the prescription in written or machine-readable form and shall include a master formula record and a compound record;

(5) Information contained in the master formulation record shall include the following:

a. Official or assigned name, strength, and dosage form of the preparation;

b. Calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients;

c. Description of all ingredients and their quantities;

d. Compatibility and stability information, including references when available;

e. Equipment needed;

f. Mixing instructions;

g. Order of mixing;

h. Mixing temperature or other controls;

i. Duration of mixing;

j. Any other pertinent instruction;

k. Labeling information in addition to legally required information found in RSA 318:47-a including:

1. Name and quantity or concentration of each active ingredient;

2. Assigned BUD;

3. Storage conditions; and

4. Prescription number;

l. Container used in dispensing;

m. Packaging and storage requirements;

n. Description of final preparation; and

o. Quality control procedures and expected results; and

(6) The compound record shall contain at least the following:

a. Official or assigned name, strength, and dosage of the preparation;

b. Master formulation record reference for the preparation;

c. Names and quantities of all components;

d. Sources, lot numbers, and expiration dates of components;

e. Total quantity compounded;

f. Name of the person who prepared the compound, who performed the quality control procedures, and approved the preparation;

g. Date of the preparation;

h. Assigned controlled or prescription number;

i. Assigned BUD;

j. Description of final preparation;

k. Results of quality control procedures such as weight range of filled capsules, pH record; and

l. Documentation of any QC issues and any ADRs reported by patient or caregiver;

(j) All significant procedures performed in the compounding area shall be covered by written standard operating procedures (SOPs) including:

(1) Facility maintenance, workflow, and cleaning;

(2) Equipment use and maintenance;

(3) Personnel;

(4) Training;

(5) Preparation;

(6) Packaging;

(7) Storage of compounded preparations;

(8) Quality assurance;

(9) Safety;

(10) Uniformity;

(11) Continuous quality improvement; and

(12) Maintain updated SDS library.

(k) The compounder shall perform the following to ensure quality control;

(1) Review calculation, ingredients, measurements and procedures; and

(2) Observe the finished preparation to ensure that it appears as expected and investigate any discrepancies and take appropriate corrective action before the prescription is dispensed to the patient.

(l) The compounder shall ensure the following compounding controls are followed:

(1) There are written procedures for the compounding of drug preparations to ensure that the finished preparations have the identity, strength, quality, and purity that they purport to have. These procedures shall be available in either written form or electronically stored;

(2) The written procedures shall be followed in execution of the compounding process;

(3) Check and document each weight and measurement;

(4) Document the identity of the person(s) actually performing the compounding;

(5) Document the name of compounder;

(6) Establish written procedures that will describe quality assurance tests or examinations to be conducted on the compounded preparation to ensure uniformity and integrity;

(7) To monitor the output and to validate the performance of those compounding processes and equipment that could be responsible for causing variability in the final compounded preparation; and

(8) Records shall be maintained with compounding records for 10 years.

(m) At the time of dispensing, the patient or the patient's agent shall be counseled about proper use, storage, handling, and disposal of the compounded preparation. The patient or the patient's agent shall also be instructed to observe and report to the compounder any changes in the physical characteristics of the compounded preparation. Counseling may be in written, oral, electronic, or other formats. The compounding pharmacist shall investigate any reported problem with a compounded preparation and take corrective action.

(n) It shall be the responsibility of the compounder to ensure that a training program has been implemented and that it is ongoing. Compounding personnel shall be trained initially and the training shall be documented.

(o) Steps in the training procedure shall include the following:

(1) All employees involved in pharmaceutical compounding shall read and become familiar with USP Chapter 795. They shall also be familiar with other relevant publications including how to read and interpret SDSs;

(2) All employees shall read and become familiar with each of the procedures related to compounding including those involving the facility, equipment, personnel, actual compounding, evaluation, packaging, storage and dispensing;

(3) All personnel who compound hazardous drugs shall be fully trained in the storage, handling and disposal of these drugs. This training shall occur before preparing or handling hazardous drugs;

(4) All training activities shall be documented. The compounder shall meet with employees to review their work and answer any questions the employee may have concerning compounding procedures;

(5) The compounder shall demonstrate the procedures for the employee and shall observe and guide the employee throughout the training process. The employee shall then repeat the procedure without any assistance from, but under the supervision of the compounder;

(6) When the employee has demonstrated to the compounder a verbal and functional knowledge of the procedure, then and only then shall the employee be permitted to perform the procedure without direct supervision. However the compounder shall be physically present and shall approve all ingredients and their quantities and the final preparation;

(7) When the compounder is satisfied with the employee's knowledge and proficiency, the compounder shall sign the documentation records to show that the employee was appropriately trained;

(8) The compounder shall continually monitor the work of the employee and ensure that the employee's calculations and work are accurate and adequately performed; and

(9) The compounder shall be solely responsible for the finished preparation.

(p) The following requirements shall be met when compounding for animal patients:

(1) Intended use on any animal patient, such as companion, performance or food, shall be determined before compounding for that patient. Because humans can consume animals as food, care shall be taken to prevent drug residue from entering the human food chain;

(2) Compounders who compound for animals shall possess knowledge of drug regulation, uses, dosing and disposition in animal patients to properly determine appropriateness of therapy; and

(3) The compounding pharmacist shall be knowledgeable about the individual species limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used in compounded preparations. For this reason, pharmacists compounding for animals shall use when possible, formulations developed specifically for animal patients. If such formulations are not available, the compounding pharmacist shall conduct a literature review to determine whether a specific component of the formula is toxic to the target species. Compounded preparations shall not to be dispensed or sold to veterinary offices for resale.

Ph 404.04 Regulatory Requirements for Sterile Compounding.

(a) A compounder shall have and maintain a permit issued by the board that allows for the compounding of sterile products as defined by the board.

(b) When a compounder prepares more than 50 dosage units for non-patient specific preparations the compounder shall be registered as a drug manufacturer or 503B with the FDA.

(c) Compounders supplying limited quantities, less than 50 dosage units, to providers for administration use shall have an MOU with the provider for each compounded product they supply to the provider. When a compounder provides a practitioner a non-patient specific preparation, the compounder shall provide the practitioner a copy of the test result for each lot provided to the practitioner.

(d) Each batch of a high risk CSP shall be assigned a unique lot number and shall be tested by an independent lab for sterility, potency, and endotoxins. Only a batch that has passed all 3 tests shall be made available to provide to a hospital or practitioner.

(e) A compounder shall not compound a sterile product of an FDA-approved product when the product is commercially available.

(f) When no commercial source of a sterile product exists, such as being listed on the FDA backorder list, the compounder shall only use USP or other USP recognized grades such as BP, JP, EP, bulk ingredients obtained from a good manufacturing practice compliant supplier. The compounder shall obtain and keep on file for at least 3 years a certificate of analysis and potency testing of all bulk ingredients used to compound each and every compounded product made with a bulk, non-sterile ingredient.

(g) A compounder who uses hazardous products shall meet state and federal requirements for handling of hazardous agents.

Ph 404.05 Sterile Quality Requirements.

(a) Each compounder shall maintain documentation that confirms staff training and competency related to proper garbing and hand hygiene, aseptic technique and related practices, and cleaning and disinfection procedures prior to compounding of any actual sterile product preparation.

(b) Each compounder shall maintain documentation that confirms that the compounder tests aseptic techniques of all staff that compounds sterile products by preparing media fill units per USP standards.

(c) Each compounder shall maintain documentation that confirms all staff that compounds sterile products are pre-qualified using media fills before compounding of actual drug preparations.

(d) When a positive media fill occurs, compounder shall perform a comprehensive investigation to identify root cause, and document the finding.

(e) When a positive media fill occurs, compounder shall institute corrective and preventive action, and document the corrective action.

(f) Each compounder shall verify that all personnel who compound sterile products are complying with gowning, gloving, and glove-tip processes consistent with USP standards by meeting the following requirements:

(1) Three glove fingertip tests shall be performed initially then annually for low and medium risk compounding ;

(2) Three glove fingertip tests shall be performed initially then every 6 months for high risk compounding; and

(3) Media fill tests shall be performed every 6 months for high risk compounding.

(g) Each compounder shall perform routine surface microbiological and fungal environmental monitoring to minimize contamination at least every 6 months, or in accordance with facilities policies.

(h) Each compounder shall perform comprehensive investigations of out-of-limit findings, as recommended by USP standards to determine root cause, followed by corrective and preventative actions at least weekly. Each compounder shall maintain all documentation of its findings.

(i) Each compounder shall perform, at least semi-annually, viable particle testing in primary engineering controls, such as laminar flow workbench, biological safety cabinet and room air according to USP standards.

(j) Each compounder shall ensure that all compounded sterile products that require refrigeration are stored in appropriate refrigeration at all times.

(k) When a compounder assigns a BUD for a sterile product that exceeds BUD limits established in USP standards, a compounder shall have laboratory testing results that support extended expiration dating for compounded sterile preparations to any patient or organization that request such documentation.

(l) Each compounder shall perform studies to determine extended expiration dates, using evidence-based and validated stability testing procedures, for compounded sterile preparations for which no extended expiration evidence exists.

(m) Each compounder shall have a policy that requires validation of new or changed facilities, equipment, processes, container types, for sterility, and repeatability.

(n) Each compounder shall have a quality assurance program to promptly address equipment problems.

(o) Each compounder shall have a quality assurance program for compounding that includes at least the following separate, but integrated, components:

(1) Training;

(2) Standard operating procedures;

(3) Documentation;

(4) Verification;

(5) Testing;

(6) Cleaning and disinfecting;

(7) Containers, packaging and repackaging; and

(8) Storage.

(p) All personnel involved in the compounding, evaluation, packaging and dispensing of compounded preparations shall be properly trained and evaluated to include:

(1) Three glove fingertip tests shall be performed initially then annually for low and medium risk compounding; and

(2) Three glove fingertip tests shall be performed initially then every 6 months for high risk compounding.

(q) Personnel shall undergo re-qualification using media fills and glove fingertip tests annually for low and medium risk sterile compounding and every 6 months thereafter for high risk sterile compounding.

(r) Each compounder shall have an action plan and alert limits for environmental monitoring.

(s) Each compounder shall develop and implement methods for improving quality based on analyzed data found in its environmental monitoring.

(t) Each compounder shall evaluate and continuously monitor the methods used for the packaging, handling, and transport of CSPs.

(u) Each compounder shall evaluate and continuously monitor the storage of CSPs to ensure compliance with appropriate storage conditions.

(v) Each compounder shall ensure drug storage refrigerators, freezers and medication storage areas have daily monitoring and documentation of temperatures.

(w) Compounder personnel shall inspect all drug storage areas routinely to ensure drugs are stored separately from food.

(x) Each compounder shall ensure all solutions, medications, equipment, and supplies located in all areas are stored according to the manufacturer or USP requirements and are inspected monthly for proper conditions of light, temperature, moisture, and ventilation.

(y) Each compounder shall ensure all outdated and unused CSPs are segregated in a separate area for return and disposal.

(z) Each compounder shall ensure only pharmacists training in sterile compounding determine whether a CSP not administered as originally intended can be used for an alternate patient or under alternate conditions.

(aa) Each compounder shall have an environmental sampling plan based on the compounding activities performed, locations to be monitored, the device used to monitor, the frequency of collection, and procedures if readings exceed established thresholds.

(ab) The 2 types of monitoring that shall be used are:

(1) Non-viable monitoring which includes particle counts, monitoring pressure or velocity difference between the buffer area, ante area and non-classified area and shall be done at least every 6 months; and

(2) Viable monitoring which detects microbial or fungal contaminants in the compounding area and shall be done using a volumetric collection method.

(ac) Monitoring, sampling, and testing for surface contamination from hazardous drugs is conducted at least every month or earlier in cases of contamination from fluid or solid dosage form spills.

(ad) Compounder shall ensure certification of its PEC complies with the requirements of USP Standards. Certification shall be done by an independent entity certified to perform the test. Each certifying entity shall leave a signed copy of the test with the compounder who shall retain the document for at least 4 years.

(ae) Each compounder shall ensure the PEC is certified every 6 months or sooner if recommended by the manufacturer.

(af) Each compounder shall ensure viable and non-viable airborne sampling occurs minimally every 6 months. Monitoring shall include all areas at risk of contamination including but not limited to inside of PEC, counters, anteroom, areas near doorways, and any pass-through, counters, storage areas, shelves, shipping and receiving areas, and employee work areas.

(ag) Each compounder shall ensure sampling data is base-lined, evaluated and documented on a routine basis as defined by USP standards.

(ah) Each compounder shall have a written plan and schedule for environmental monitoring.

(ai) Each compounder shall have a written environmental plan that adequately evaluates the various controlled air environment areas including the PEC, buffer area, and anteroom.

(aj) Compounder facility personnel, or external personnel, who complete the environmental monitoring shall be appropriately trained and certified by a national certification entity.

Ph 404.06 Compounding Environment.

(a) Each compounder shall ensure there is sufficient space for the type and amount of compounding done.

(b) Each compounder shall ensure there is appropriate space for orderly placement of equipment and materials to prevent mix-ups between ingredients, containers, labels, in-process materials and finished preparations.

(c) Each compounder shall ensure it has procedures to prevent cross-contamination.

(d) Each compounder shall ensure areas used for sterile preparation are separate and distinct from areas used for non-sterile preparation.

(e) Each compounder shall have a well-lighted compounding environment.

(f) Each compounder shall ensure all heating, ventilation and air conditioning systems are controlled to maintain a constant temperature 24 hours per day, 7 days per week.

(g) Each compounder shall maintain a bulk storage area that is adequately arranged and proper temperature and humidity maintained.

(h) Each compounder shall supply hot and cold potable water for hand and equipment washing in the compounding area, and soap or detergent and single-use towels or driers shall be readily available.

(i) Each compounder shall ensure all compounding areas are maintained in a clean and sanitary condition.

(j) When compounder uses hard-wall construction, the finished surface shall provide a non-porous, durable and washable surface.

(k) The compound area shall meet the following requirements:

(1) All ceilings shall be smooth, impervious, free from cracks and non-shedding, such as plastic covered clean room grade ceiling tiles, and all tiles shall be sealed;

(2) All floors shall be smooth, impervious, free from cracks and non-shedding, and the floor must be of seamless vinyl;

(3) All fixtures shall be smooth, impervious, free from cracks and non-shedding. All fixtures shall be mounted to wall in a way that seals any space between wall and fixture;

(4) All shelving shall be smooth, impervious, free from cracks and non-shedding;

(5) Counters shall be smooth, impervious, free from cracks and non-shedding;

(6) All cabinets shall be smooth, impervious, free from cracks and non-shedding;

(7) Ceiling to wall junctures shall be covered or caulked to avoid cracks;

(8) Inlaid ceiling panels shall be impervious and hydrophobic;

(9) Ceiling panels shall be caulked around the perimeter to seal them to frame;

(10) Floors shall be overlaid with wide sheet vinyl flooring with heat welded seams and coving to the sidewall;

(11) There shall be no dust-collecting overhangs;

(12) There shall be no windowsills;

(13) Exterior lens surface of ceiling light fixtures shall be smooth, mounted flush, and sealed;

(14) There shall be no sinks in primary and secondary compounding areas;

(15) There shall be no floor drains in primary and secondary compounding areas;

(16) Carts shall be made of stainless steel wire or sheet metal with cleanable casters;

(17) Carts shall be mobile;

(18) All surfaces shall be designed to provide effective cleaning;

(19) All surfaces shall be resistant to damage by cleaning agents;

(20) There shall be no cardboard containers in buffer area at any time;

(21) There shall be no computers, printers, radios and refrigerators in the buffer area at any time;

(22) The bulk storage area shall be maintained in a clean and sanitary condition;

(23) Trash shall be disposed of in a safe, sanitary and timely manner; and

(24) All components, containers and equipment shall be stored off the floor in a manner to prevent contamination and permit inspection and cleaning of the compounding and storage area.

(l) Each compounder shall ensure equipment is of appropriate design and size for the compounding that is performed.

(m) Each compounder shall ensure that all equipment is of appropriate design such that the surface that contact pharmaceutical components, in-process materials or finished preparations is not reactive, additive or adsorptive.

(n) Each compounder shall ensure that all equipment is thoroughly cleaned immediately after use to avoid cross-contamination.

(o) Each compounder shall ensure all equipment is stored to prevent it from contamination and is located to facilitate its use, maintenance, and cleaning.

(p) Each compounder shall ensure all equipment used for allergenic ingredients is appropriately handled, cleaned and stored immediately after use.

(q) Each compounder shall ensure all work surfaces are cleaned of loose materials and residue from spills before compounding.

(r) Each compounder shall ensure all floors in the buffer area and ante area are mopped daily with a cleaning and disinfecting agent at a time when no aseptic compounding is in progress.

(s) Each compounder shall approve all cleansing and sanitizing agents considering compatibilities, effectiveness, and presence of inappropriate or toxic residues.

(t) Each compounder shall ensure the following requirements are met:

(1) Mops, wipes, sponges, and other cleaning materials shall be non-shedding and dedicated for use only in the sterile compounding area;

(2) Cleaning tools shall be replaced as soon as they are identified as unsuitable for use;

(3) All cleaning materials shall be disposable and discarded after one use;

(3) All trash shall be collected in suitable plastic bags and removed on a daily basis with minimal agitation;

(4) Workspaces shall be cleaned and sanitized daily including all buffer room carts, equipment, workbenches, work surfaces, and floors, and document the activity;

(5) Storage shelving in buffer and ante areas shall be emptied of all supplies, cleaned, and sanitized at planned intervals at least monthly;

(6) Walls and ceilings in buffer and ante areas shall be cleaned at least monthly; and

(7) All equipment shall be clean, properly maintained, validated and documented at appropriate intervals as defined by USP Standards.

Ph 404.07 Engineering Controls.

(a) Each compounder shall ensure the PEC, LAFW and BSCs provide ISO Class 5 air quality;

(b) Each compounder shall ensure the buffer room maintains a minimum of an ISO Class 7 air quality;

(c) Each compounder shall ensure the buffer room is designed to reduce the risk of contaminants being blown into the primary compounding area, or PCA. To be considered a clean room, buffer area must meet specific air quality, HEPA filtration, air changes per hour, and room pressure differentiation criteria to provide at least ISO Class 7 air quality.

(d) Each compounder shall ensure that within the buffer area, the PEC should be kept away from excess traffic, doors, air vents, or anything that could introduce contaminates into the workbench.

(e) Each compounder shall ensure that the anteroom is separate from buffer area.

(f) Each compounder shall ensure that the anteroom provides ISO Class 8 air quality, or ISO Class 7 air quality, depending on the connecting buffer area.

(g) Each compounder shall ensure the anteroom area should store an adequate amount of gowning supplies but should not be part of high traffic area or corridor.

(h) Each compounder shall ensure the anteroom is used to un-carton and sanitize all supplies to be taken into buffer area.

(i) Each compounder shall ensure sure the anteroom contains:

(1) Hand sanitizing equipment;

(2) Proper gowning equipment and space to accommodate gowning activities;

(3) Faucet handles that shall be designed to be hands-free; and

(4) That the buffer area can be accessed without the use of hands.

(j) Each compounder that only compounds low and/or medium risk preparations, the ante room may be in the same area as the buffer room, separated by a line of demarcation. However, a separate ante room shall be the preferred method.

(k) Each compounder that compounds high risk preparations, the buffer room and the ante room shall be 2 separate rooms.

(l) Each compounder shall ensure all supplies brought into the buffer area are non-permeable, non-shedding, and resistant to disinfectants.

(m) Each compounder shall ensure all materials exposed to patient care areas are kept out of the buffer area.

(n) Each compounder shall ensure the PECs are cleaned and disinfected at the beginning of each shift, before each batch, at least every 30 minutes during compounding, when surfaces are visibly soiled, and when surface contamination is known or even suspected.

(o) Each compounder shall ensure all interior working surfaces are cleaned and disinfected of LAFW from top to bottom, back to front, away from the HEPA filter. Cleaning shall be performed with purified water, and disinfecting with sterile 70% isopropyl alcohol or similar antimicrobial, residue-free sanitizing agent.

(p) Each compounder shall ensure nothing shall be permitted to come in contact with the HEPA filter. This includes cleaning solutions, aspirate from syringes, or glass from ampules, which shall not be broken towards the filter.

(q) Each compounder shall ensure air exchange with the surrounding environment shall not occur unless the air is first passed through a microbial retentive filter such as a HEPA system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where volatile hazardous drugs are prepared, the exhaust air from the isolator shall be appropriately removed by properly designed building ventilation.

Ph 404.08 Compounding Procedures.

(a) Each compounder shall ensure that all personnel adhere to the following when they are in the LAFW or buffer areas:

(1) No smoking, food, drink, or chewing gum shall be allowed in the buffer area at any time;

(2) No jewelry shall be worn on the hands or wrists and there shall be no visible piercings;

(3) No make-up shall be worn in the buffer area as it can shed particles;

(4) Before putting on gloves, the nails shall be cleaned, and the hands, wrists, and forearms shall be washed thoroughly for at least 30 seconds with warm water and antimicrobial skin cleanser;

(5) Personnel shall appropriately utilize gowns, masks, gloves, hair covers, and shoe covers;

(6) No paper, pens, labels, or trays shall be placed in the workbench; and

(7) No objects that shed particles shall be brought into the buffer area such as cardboard cartons, paper towels, and cotton items.

(b) Each **c**ompounder shall ensure when cleaning and disinfecting the interior work surfaces of the LAFW it is done from top to bottom, back to front, away for the HEPA filter.

(c) Each compounder shall ensure personnel check the quality, purity, amount, and identity of all ingredients.

(d) Each **c**ompounder shall ensure all personnel use the correct compounding procedures when compounding sterile products, and periodically disinfect gloves with sterile 70% isopropyl alcohol and allow them to dry thoroughly before continuing.

(e) Each compounder shall ensure that open and partially used containers are properly labeled and stored.

(f) Each compounder shall ensure the following:

(1) CSP has an appropriate BUD that is identified on all product labels;

(2) When the BUD exceeds USP standards, it is based on scientific criteria;

(3) Packaging is appropriate for sterility and stability;

(4) Product labels are appropriate and complete for safe use; and

(5) Products are visually inspected for physical integrity during and after compounding, and a final check of the CSP is performed.

(g) Each compounder shall ensure any deficiencies in compounding procedures can be rapidly identified and corrected.

(h) Each compounder shall ensure that finished compounded products are maintained in a separate area away from the active compounding area, and that no more than 2 entries into any one sterile container or sterile administration device.

(i) Each compounder shall ensure all compounding activity only involves closed or sealed packaging systems.

(j) In the absence of stability and sterility testing of any CSP the compounder shall use BUD based on USP standards as defined for the following CSPs:

(1) Low risk compounded product storage shall not exceed 48 hours at room temperature, 14 days at cold temperature or 45 days in a frozen state if the stability of the product allows;

(2) Medium risk compounded product storage shall not exceed 30 hours at controlled room temperature, 9 days at cold temperature or 45 days in a frozen state;

(3) High risk compounded product storage shall not exceed 24 hours at room temperature**,** 3 days at cold temperature or 45 days in a frozen state.

Ph 404.09 Records Management.

(a) Compounder shall maintain the following records related to compounding of sterile products for at least 4 years:

(1) PEC certification records;

(2) GAP analyses; and

(3) Detailed formulation record of each sterile compounded preparation that includes:

a. Name of preparation, strength and dosage form;

b. All ingredients and their quantities;

c. Equipment used for the preparation;

d. Admixing instructions to include order of mixing, temperatures, duration of mixing and other pertinent factors;

e. Assigned beyond-use date;

f. Container used;

g. Storage requirements; and

h. Quality control procedures.

(b) Each compounder shall have procedures developed for the facility, equipment, personnel, preparation, packaging and storage of compounded preparation to ensure accountability, accuracy, quality, safety, and uniformity in compounding.

(c) Each compounder shall have a procedure for recalls. The recall file shall be maintained with information concerning any applicable recalled products affecting the pharmacy.

(d) Each compounder shall perform and maintain a quality control history and quality assurance trend reports on a quarterly basis and upon request.

(e) Each compounder shall maintain documentation that confirms that sterile media used is certified by the manufacturer to be sterile and guaranteed to promote growth.

(f) Each compounder shall maintain detailed reports on the incidence of positive media test results and the follow-up retests after corrective action is completed.

(g) Each compounder shall provide a guaranteed shelf life upon delivery. This date shall be based on USP Standards, or based on established scientific criteria.

(h) Each compounder shall document processes and procedures including shipping validation studies to ensure that preparations leaving the site retain their integrity and stability through the shipping cycle.

(i) Each compounder shall ensure that all personnel annually receive live training and visual process validation including written documentation of both processes.

(j) Each compounder shall maintain documentation that it's cleaning methods and agents are effective in preventing contamination of the sterile preparations area.

PART Ph 405 STANDARDS OF PRACTICE FOR NUCLEAR/RADIOLOGIC PHARMACY

Ph 405.01 Purpose. The practice of nuclear pharmacy is hereby recognized as a specialty of pharmacy practice, regulated by the state board of pharmacy. As such, the following rules are included to address those areas specific or unique to this specialty practice.

Ph 405.02 Definitions.

(a) "Authentication of product history" means identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical or other drug.

(b) "Nuclear pharmacy" means a pharmacy which provides radiopharmaceutical services.

(c) "Practice of nuclear pharmacy" means a patient-oriented service that embodies the scientific knowledge and professional judgment required to improve and promote health through the assurance of the safe and efficacious use of radiopharmaceuticals and other drugs.

(d) "Quality assurance procedures" means all activities necessary to guarantee the integrity of the process used to provide radiopharmaceutical services, including authentication of product history and maintenance of all records as required by the department of health and human services, bureau of radiological health.

(e) "Quality control testing" means the performance of chemical, biological and physical tests on compounded radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals.

(f) "Radiopharmaceutical" means any drug which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons. The term includes any nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such substance, but does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides. The term also includes any biological product which is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

(g) "Radiopharmaceutical service" means the procurement, storage, handling, compounding, preparation, labeling, quality control testing, dispensing, distribution, transfer, record keeping and disposal of radiochemicals, radiopharmaceuticals and ancillary drugs.

Ph 405.03 General Requirements for Pharmacies Providing Radiopharmaceutical Services.

(a) A permit to operate a pharmacy which provides radiopharmaceutical services shall only be issued to a person who is, or who employs, a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals and ancillary drugs shall be under the direct supervision of a qualified nuclear pharmacist, who shall be in personal attendance when the pharmacy is open for business. The pharmacist-in-charge shall be responsible for all operations of the pharmacy.

(b) The nuclear pharmacist who licenses the pharmacy shall hold a current license issued by the board, and be either certified as a nuclear pharmacist by the board of pharmaceutical specialties or satisfy each of the following requirements:

(1) Meets minimal standards of training for status as authorized user of radioactive material, as specified by the department of health and human services, bureau of radiological health;

(2) Has successfully completed a minimum of 200 contact hours of instruction in nuclear pharmacy and the safe handling and use of radioactive materials from a nationally accredited college of pharmacy, or other training program recognized by the department of health and human services, bureau of radiological health;

(3) The 200 hours of instruction referenced in (2) above shall be apportioned as follows:

a. Radiation physics and instrumentation, 85 hours;

b. Radiation protection, 45 hours;

c. Mathematics pertaining to the use and measurement of radioactivity, 20 hours;

d. Radiation biology, 20 hours; and

e. Radiopharmaceutical chemistry, 30 hours;

(4) Has attained a minimum of 500 hours of clinical/practical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist in, but not limited to, the following areas:

a. Procuring radioactive materials;

b. Compounding radiopharmaceuticals;

c. Performing routine quality control procedures;

d. Dispensing radiopharmaceuticals;

e. Distributing radiopharmaceuticals;

f. Implementing basic radiation protection procedures; and

g. Consulting and educating the nuclear medicine community, patients, pharmacists, other health professionals, and the general public; and

(5) Has submitted an affidavit of experience and training to the board.

(c) The permit to operate a nuclear pharmacy shall be effective only so long as the pharmacy also holds a current license issued by the department of health and human services, bureau of radiological

health. Copies of the bureau of radiological health inspection reports shall be available at the pharmacy for board inspection.

(d) Nuclear pharmacies shall have adequate space and equipment, commensurate with the scope of services required and provided and meeting minimal space requirements established for all pharmacies in the state.

(e) All pharmacies handling radiopharmaceuticals shall include, but not be limited to, the following areas:

(1) Radiopharmaceutical preparation/dispensing area;

(2) Radioactive material shipping/receiving area;

(3) Radioactive material storage area; and

(4) Radioactive waste decay area.

(f) The application for a permit to operate a nuclear pharmacy shall be the same as in Ph 304.01 and Ph 304.02.

(g) The nuclear pharmacy professional service area shall be secured from unauthorized personnel and shall be totally enclosed and lockable.

(h) Nuclear pharmacies shall maintain records of acquisition, inventory and disposition of all radioactive drugs and other radioactive materials in accordance with the board and the department of health and human services, bureau of radiological health statutes and rules.

(i) A radiopharmaceutical shall be dispensed only to a licensed practitioner authorized by the department of health and human services, bureau of radiological health to possess, use and administer such drug. A radiopharmaceutical shall be dispensed only upon receipt of a prescription or medication order from such licensed practitioner. Otherwise, a radiopharmaceutical may be transferred to a person who is authorized to possess and use such drug for non-clinical applications.

(j) A nuclear pharmacy, upon receiving an oral prescription order for a radiopharmaceutical, shall immediately have the prescription order reduced to writing, or recorded in a data processing system.

(k) The writing or record required by (i) above shall contain at least the following:

(1) The name of the institution and prescriber, or prescribers' agent;

(2) The date of dispensing and the calibration time of the radiopharmaceutical;

(3) The name of the procedure;

(4) The name of the radiopharmaceutical;

(5) The dose or quantity of the radiopharmaceutical;

(6) The serial number assigned to the order for the radiopharmaceutical;

(7) Any specific instructions;

(8) The initials of the person who received the order; and

(9) The initials of the person who dispensed the order.

(l) Whenever an order is for a therapeutic or blood-product radiopharmaceutical, the patient's name shall be obtained and recorded prior to dispensing.

(m) The immediate outer container shield of a radiopharmaceutical to be dispensed shall be labeled with:

(1) The name and address of the pharmacy;

(2) The name of the prescriber;

(3) The date of dispensing;

(4) The serial number assigned to the order for the radiopharmaceutical;

(5) The standard radiation symbol;

(6) The words "Caution Radioactive Material";

(7) The name of the procedure;

(8) The radionuclide and chemical form;

(9) The amount of radioactivity and the calibration date and time;

(10) If a liquid, the volume;

(11) If a solid, the number of items or weight;

(12) If a gas, the number of ampules or vials;

(13) Molybdenum 99 content to USP limits; and

(14) The name of the patient or the words "Physician's Use Only" in the absence of a patient name.

(n) When the prescription is for a therapeutic or blood-product radiopharmaceutical, the patient name shall appear on the label. The requirements of this paragraph shall be met when the name of the patient is readily retrievable from the physician upon demand.

(o) The immediate inner container label of a radiopharmaceutical to be dispensed shall be labeled with:

(1) The name of the pharmacy;

(2) The standard radiation symbol;

(3) The words "Caution Radioactive Material";

(4) The identity of the radionuclide;

(5) The chemical form;

(6) The name of the procedure; and

(7) Serial number of the radiopharmaceutical.

(p) When a radiopharmaceutical is dispensed under the authority of an investigational new drug application (IND), the nuclear pharmacy records shall include an investigator's protocol for the

preparation of the radiopharmaceutical, and a letter from the manufacturer or sponsor indicating that the physician requesting the radiopharmaceutical is a qualified investigator.

(q) Each nuclear pharmacy shall have a current copy of the United States Pharmacopeia/National Formulary (USP/NF), USP-DI, and a current copy of state and federal rules and regulations governing the safe storage, handling, use, dispensing, transport and disposal of radiopharmaceuticals.

Ph 405.04 Minimum Equipment. The pharmacy shall have at least the following equipment:

(a) A radionuclide dose calibrator;

(b) A refrigerator;

(c) A single or multiple channel scintillation counter with well-type NaI (Tl) or Ge (Li) detector;

(d) A radiochemical fume hood and filter system with air sampling equipment;

(e) An area survey meter;

(f) At least 2 Geiger Mueller survey meters including one high-range meter;

(g) A microscope and hemacytometer;

(h) A laminar air flow hood and appropriate supplies to ensure sterile practices for parenteral solutions;

(i) Syringe and vial radiation shields;

(j) A lead-shielded drawing station;

(k) Decontamination supplies;

(l) Supplies to perform quality assurance testing;

(m) Lead transport shields for syringes and vials; and

(n) United States Department of Transportation approved USA Type A - 7A transport containers and other labels and supplies for shipping radioactive materials.

Appendix

Rule	Statute Implemented
Ph 401.01	RSA 318:5-a, I, III, V, VII, VII-a
Ph 401.03 – Ph 401.05	RSA 318:26
Ph 401.06 - Ph 401.07	RSA 318:5-a, II
Ph 402.01 – Ph 402.04	RSA 318:5-a, VI, VII
Ph 403.01 - Ph 403.02	RSA 318:29, I, II, IV, V
Ph 403.02	RSA 318:5-a,VII-a
Ph 403.03 – 403.13	RSA 318:25, III
Ph 404	RSA 318:5-a, II, IV-a
Ph 405	RSA 318:5-a, II, IV-a